

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

**Amendments to the Drawings:**

In view of the Examiner's objection, Applicants submit herewith new Fig. 12, to be inserted following Fig. 11.

In Fig. 12, the distal end of an elongates arm having a ball, and the adhesive pad having a socket, is shown.

**Attachments:**

Fig. 12 is attached as an appendix hereto.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

### **REMARKS**

Claims 3-6, 8, 14, 21, 22, and 27-50 are pending. Claims 3, 4, 14, 21, 22, 27-37, 43-45, 49 and 50 are withdrawn as being drawn to non-elected subject matter. The amendment to claim 8 is submitted in order to address the formal rejection issued by the Examiner in the outstanding Office Action of November 9, 2009. No new matter has been incorporated into the application as a result of the amendment made herein.

Entry of the amendment is requested under 37 C.F.R. 1.116, as the amendment is merely directed to matters of form and raises no new issues. Likewise, entry of revised Fig. 12 and the previously submitted specification amendments is requested, as discussed below.

#### ***Objection to the Drawings***

At page 2 of the Office Action, the Examiner refuses to enter the new Fig. 12 as showing an object which is not described in the specification. Specifically, the Examiner directs attention to "the object to the left of socket 117". The Examiner states:

The drawing submitted 8/10/09 (of Fig. 12) will not be entered. The drawing shows material that was not in the application when originally filed. Specifically, the object to the left of the socket 117 is not described in the specification. The pad as shown in the original drawings (element 144, Fig. 7) simply shows the pad with a ball. The claims recite more than the pad.

Applicants submit herewith another version of Fig. 12 for the Examiner's consideration, wherein the "object to the left of socket 117" is now clearly identified as a portion of the socket itself. The Examiner's attention is directed to Figs. 7 and 8, wherein flexible arm(s) 121 and 122, analogous in function to the

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

objected-to “object”, are utilized to co-act with the socket recesses 138 and 139 to retain the ball portion of the connector. The embodiment illustrated in Fig. 12 is merely a reflection of the members of the socket portions illustrated in Figs. 7 and 8.

One of skill in the art would recognize that a socket joint for a ball and socket connection must have a co-acting portion to retain the ball in the socket.

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)... If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “the description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”)...The description need only describe in detail that which is new or not conventional. **MPEP 2163, II, 3(a).**

Withdrawal of the objection and entry of the new Figure 12 is requested.

### ***Objection to the Specification***

At page 3 of the Office Action, the Examiner has objected to the specification amendments filed in support of new Fig. 12.

The substitute specification filed 6/15/09 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: the drawing of Fig. 12 has not been entered, therefore the description will not be entered.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

Applicants request reconsideration of the objection and entry of the specification amendments for the same reasons as described above.

**Rejection under 35 U.S.C. §112**

Claim 8 stands rejected under 35 U.S.C. §112, second paragraph as failing to have appropriate antecedent basis for the term “connector”. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof, in view of the accompanying amendment.

**Rejection under 35 U.S.C. §103(a) over Taylor et al.**

**in view of Coffey**

Claims 5, 6, 8, 38-42 and 46-48 stand rejected under 35 U.S.C. §103(a) as obvious over Taylor et al. (U.S. Patent No. 6,394,951) in view of Coffey (U.S. Patent No. 2,003,629). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiencies of Taylor et al. were discussed at length in Applicants' previous response of August 23, 2007, and in their Request for Pre-Appeal Brief Conference filed September 17, 2008, and are reiterated herein.

In the present Office Action, the Examiner recognizes that Taylor et al. fail to disclose or suggest first and second socket joints having a rotatable connection (Office Action, page 5).

The Examiner then points to Coffey and states:

Coffey teaches a rotatable connection between the elongate arms and the pad, and the adhesive pad is rotatable around the ball

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

about at least two axes (slight rotation is possible along two axes). It would have been obvious to one of ordinary skill in the art to use the rotatable connection of Coffey with the device of Taylor as this allows smooth action and aids in the use of the jaws (page 1, ll. 47-55, page 2, col. 1, ll. 1-3). (Emphasis added).

Applicants traverse the Examiner's findings and conclusion for several reasons.

First, it is respectfully submitted that Coffey is non-analogous art as to Taylor et al.

Coffey discloses a battery terminal cleaning tool. In contrast, Taylor et al. disclose a surgical instrument for coronary artery bypass surgery. Applicants respectfully submit that the cited reference fields-of-use are so far removed, one from the other, that one skilled in the art (whichever art that might be) would not have looked to one reference to modify the other.

Withdrawal of the rejection is requested on this basis alone.

In response to Applicants' assertion of non-analogous art, the Examiner explains:

Applicant's arguments filed 6/15/09 have been fully considered but they are not persuasive. The applicant argues Coffey is non-analogous art with Taylor, therefore a 103 rejection is improper. The examiner respectfully disagrees that the 103 rejection is improper. That is, it has been held that the determination that a reference is from a non-analogous art is twofold. First we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood*, 202 USPQ 171, 174. In this case, Coffey teaches a rotatable connector in the field of approximation devices with elongate arms.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

Applicants respectfully submit that the Examiner is improperly recasting the “field of Applicants’ endeavor”. At page 1 of the specification, Applicants state:

The present invention is directed to a tissue approximation device that is capable of maintaining approximation of a wound without substantial eversion of the edge surfaces of the wound and without requiring the physician or health care attendant to manually secure the device.

In contrast, Coffey discloses:

My invention relates to what I term an in and out terminal cleaning tool which is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface. The tool is especially adapted for cleaning storage battery terminals and their connectors... (page 1, column 1, lines 1-7).

Clearly, Coffey fails the first prong of the test for analogous art recited in *In re Wood, Id.* A battery terminal cleaner is certainly not “within the field of the inventor’s endeavor”, which is a tissue approximation device.

Likewise, Coffey fails the second prong of the test for analogous art, i.e. “whether the reference is reasonably pertinent to the particular problem with which the inventor was involved”.

As set forth in the above-quoted portion of the present specification, the present device is configured to maintain “approximation of a wound without substantial eversion of the edge surfaces of the wound”. In contrast, the Coffey device “is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface”.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

Cleaning of a cylindrical or conical surface is entirely unrelated to tissue approximation. The Examiner's statement that "Coffey teaches a rotatable connector in the field of approximation devices with elongate arms" is entirely incorrect. Coffey fails to disclose tissue approximation whatsoever. In this case, by focusing only on the attachment portions of the Coffey device, the Examiner is guilty of impermissibly picking and choosing only so much of the prior art disclosure as supports her rejection, to the exclusion of the remaining reference teachings.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). **MPEP 2141.03 VI.**

When considered as a whole, Coffey would not lead the skilled artisan to modify a tissue approximation device in any way. Withdrawal of the rejection is requested on this basis alone.

Second, Coffey fails to disclose adhesive pads whatsoever, despite the Examiner's indication to the contrary. Fig. 1 of Coffey illustrates the tool described therein. In particular the ball and socket mounted portions 32 and 33 are described as "circular jaws" and "their edges", respectively (page 1, col. 2, lines 41-47). One skilled in the art would certainly not interpret this disclosure to mean that items 32 and 33 are adhesive pads, or even the equivalents thereof.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

Accordingly, a full and fair reading of Coffey would not have led the skilled artisan to modify the device of Taylor et al. *In re Wesslau, Id.*

Further, in view of the extremely delicate nature of the surgery to be performed as set forth in Taylor et al., i.e. open heart surgery, the skilled artisan would not have been motivated to look to Coffey, directed to an automotive tool, with any expectation of success in improving an apparatus for heart surgery (Taylor et al.). Additional axes of movement would likely be detrimental to the surgical procedure to be performed with the Taylor et al. device, where the utmost accuracy in positioning would be required. Note the Taylor et al. disclosure in Fig. 2, wherein the snap in members 16 are restricted in movement capability by the two posts 18 (col. 14, lines 20-28).

The Examiner's proposed modification of Taylor et al. runs afoul of the decision in *W.L. Gore & Associates, Inc. v. Garlock, Inc., Id.*, that is:

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

In this case, the skilled artisan would not have been motivated to modify Taylor et al., which is directed to a tool for very fine and accurate positioning against heart tissue, in the manner of an automotive tool, which is configured for gross movements, and in this case for scraping-off corrosion from metal.

Withdrawal of the rejection is requested.

Application No.: 10/674,653

Response Dated: February 12, 2010

Response to Office Action dated: November 9, 2009

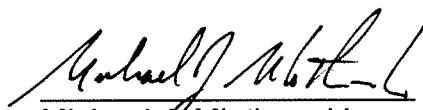
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (13926).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: February 12, 2010



Michael J. Mlotkowski  
Attorney for Applicants  
Registration No. 33,020  
(703) 584-3270

POST OFFICE ADDRESS to which correspondence is to be sent:

Roberts, Mlotkowski Safran & Cole  
P.O. Box 10064  
McLean, VA 22102

Attachment: Fig. 12 (New Sheet)